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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

KEMMERER, ELIZABETH

ART UNIT PAPER NUMBER

1646

DATE MAILED: 03/12/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/945,182

Applicant(s)

CELESTE ET AL.

Examiner

Elizabeth C. Kemmerer, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 17,18,20 and 27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17,18,20 and 27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of Application, Amendments, And/Or Claims***

The amendment filed 29 January 2003 (Paper No. 6) has been entered in full. Claims 1-16, 19, 21-26 and 28 are canceled. Claims 17, 18, 20 and 27 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Withdrawn Objections And/Or Rejections***

The objection to claims 17, 18, 20 and 27 for informalities as set forth at pp. 5-6 of the previous Office Action (Paper No. 4, 30 October 2002) is *withdrawn* in view of the amended claims (Paper No. 6, 29 January 2003).

The application is now fully in compliance with the sequence rules, 37 CFR 1.821-1.825.

The statuses of the cited U.S. Patent applications have been properly updated.

### ***Double Patenting***

Claims 17, 18, 20 and 27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6-10 and 17-20 of U.S. Patent No. 6,027,919. Although the conflicting claims are not identical, they are not patentably distinct from each other for the reasons set forth at pp. 2-3 of the previous Office Action (Paper No. 4, 30 October 2002).

Applicant's arguments (pp. 8-9, Paper No. 6, 29 January 2003) have been fully considered but are not found to be persuasive for the following reasons. Applicant argues that the public policy justifying the doctrine, to prevent the improper extension of 'right to exclude' conferred by a patent due to the dates when the patents in question would expire, no longer exists. However, the improper extension of 'right to exclude' is only one of the two issues addressed by an obviousness-type double patenting rejection. The other regards common ownership, and protecting the public from multiple infringement suits from multiple owners. Note the following, quoted in the previous Office Action:

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent **and to prevent possible harassment by multiple assignees**. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground **provided the conflicting application or patent is shown to be commonly owned with this application**. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b). (emphasis added)

Therefore, the obviousness-type double patenting rejection was properly made, and is maintained.

**35 U.S.C. § 112, First Paragraph**

Claims 17, 18 and 27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the recited polypeptides and compositions wherein the recited BMP-12 related polypeptides comprise at least amino acids 3 to 104 of SEQ ID NO: 2 (BMP-12) or SEQ ID NO: 4 (MP52) or amino acids 19 to 120 of SEQ ID NO: 26 (BMP-13), does not reasonably provide enablement for the recited BMP-12 related polypeptide limited only by the name of the polypeptide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The basis of this rejection is set forth at pp. 3-5 of the previous Office Action (Paper No. 4, 30 October 2002).

Applicant's arguments (p. 9, Paper No. 6, 29 January 2003) have been fully considered but are not found to be persuasive for the following reasons. Applicant argues that amending the claim to recite that the BMP-12 related polypeptide is chosen from BMP-12, BMP-13 and MP52 has obviated the rejection. However, the claims are not limited to what has been indicated as enabled. The claims do not recite specific structural limitations for the polypeptides other than their names. The specification defines "BMP-12" as preferably having an amino acid sequence of SEQ ID NO: 2, but also encompassing mutants and/or variants which exhibit the ability to form tendon and/or ligament. See p. 2, first paragraph; p. 4, last paragraph; paragraph bridging pp. 7-8. Also, it is clear from the claims that a claim reciting "the protein is chosen from BMP-12, BMP-13, and MP52" is broader than just SEQ ID NOS: 2, 4, and 26, since

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separate claims are presented which merely recite protein names, and other which recite SEQ ID NOS:. See claims 20 and 27, for example. Therefore, claims 17, 18 and 20 are interpreted as being broader than the sequences indicated as enabled, and the rejection is maintained.

### ***Claim Objections***

Claim 20 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 27 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 18. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). The scopes of the two claims are identical.

Claim 20 is objected to because of the following informalities: Claim 20 contains the clerical error "fromSEQ". Appropriate correction is required.

### ***Conclusion***

No claims are allowed.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D. whose telephone number is (703) 308-2673. The examiner can normally be reached on Mon. - Thurs., 6:30 to 4:00, and alternate Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne L. Eyler, Ph.D. can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

*Elizabeth C. Kemmerer*

ECK  
March 12, 2003

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